UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,158	08/01/2001	Yong Hua Zhu	LOMAU.138A	7213

20995 7590 02/14/2003

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
ROBERTS, PAUL A	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 02/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/921,158	Applicant(s) ZHU, YONG HUA	
	Examiner Paul A Roberts	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *3,4 and 26-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 6-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6, 7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Claims 3, 4, & 25-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

Specification

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the arms must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

4. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the arms as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing.

5. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The retractor arms do not provide to access an access passage. While it is true the arms block the access passage, the specification (page 14, last paragraph) does not provide enablement for the step of providing access.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, & 10-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhu Yon Hua WO 97/20505. Zhu discloses a method for closing a wound (line 14, page 13) in an artery utilizing a guidewire (20), the guidewire extends through the wound and a portion extends out of the wound (figure 4.), a catheter with a side hole (80) (the catheter is not labeled but it the rod element shown in figure 5), a source of suction (line 12, page 15) in communication with a lumen, a retractor (3) that has two arms/handles (43,45.) The retractor is coupled to the catheter (figure 5.) A hemostat material, (22-23, page 13) is mounted to the catheter. Blood will be

drawn into the side holes when the hemostat device is placed into an artery. The retractor provides access via the side holes to the outer wall of the artery, the hemostat material is placed into contact with the artery (19-20, page 10.) The catheter, guidewire, and retractor are then removed (27-35, page 13.)

8. Regarding claim 2, the hemostat material is held in place until it is soaked with blood. Since the hemostat is placed in the artery, it will necessarily become soaked with blood. Note, an item need not absorb a fluid to be considered soaked.

9. Regarding claim 10, the Zhu device inherently discloses the step of locating the wound. The implement/guidewire extends through the wound and a portion of the guidewire extends out of the wound (figure 4.) A hemostat is provided (page 13, line 19; the balloon.) The balloon is positioned in the artery (line 25, page 13), since the balloon is part of the guidewire and the guidewire is positioned in the artery. The hemostat material is advanced through the wound since the guidewire, to which the hemostat is attached, is advanced through the wound.

10. Regarding claim 11, the Zhu device contains an access passage to the wound (figure 4.) The catheter is said passage.

11. Regarding claim 12, the Zhu device contains a retractor (3) that has two arms/handles (43, 45.) Since these arms help position the device(7, page 7), the arms help provide the surgeon access into the artery via the catheter comprising said arms.

12. Regarding claim 13, the Zhu device comprises the step of inserting the catheter and then inflating/positioning the balloon/hemostat (fig. 4, 6.) This sequence of steps inherently includes clearing a field that surrounds the wound. These steps occur prior to positioning the hemostat

because inserting the device wound inherently clear the field (the field being the debris (cells, fibrin, foreign matter, etc.) lodged in the wound.)

13. Regarding claim 14, the balloon is held in the wound while the balloon is soaked by the blood (20, figure 4.)

14. Regarding claim 15, the surgical implant comprises a guidewire (figure 4.)

15. Regarding claim 16, the surgical implant comprises a catheter (18, page 13.)

16. Regarding claim 17, the tip of the catheter extends through the wound (catheter is the tube inside of 15, figure 4.)

17. Regarding claim 18, the catheter is removed from the wound after the hemostat material is disposed adjacent the wound (27-33, page 13.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. Claim 5 and claim 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu Yon Hua WO 97/20505 in view of Weldon et al. US 5,419,765. Zhu discloses all of claim 1, but fails to disclose the step of adding an adhesive to aid the clotting process. The use of an adhesive for use with clotting is well known in the art. Patents US 5.419.765, 5.728.132 6.325.789, 5.649.959 all disclose using an adhesive to help percutaneous hemostat closing. For example, Weldon et al. discloses that thrombin (a biological adhesive) should be ejected from the second

lumen of the catheter to reduce healing time (last paragraph, column 5.) At the time of the invention, it would have been obvious to one of ordinary skill in art to use the Weldon hemostat adhesive with the Zhu homeostasis device, because Weldon et al. disclose that the use of a hemostat adhesive in conjunction with another hemostat device (a balloon in this example) help further reduce healing time.

19. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu Yon Hua WO 97/20505, in view of Mikus et al. US 6,033,413. Zhu discloses all of claim 1, but does not disclose that the catheter should be made with a viewing portion. Though the figures suggest that the catheter may be clear (and most catheters are clear) it is not explicitly stated in the text of the reference. Mikus et al. disclose a surgical catheter that has a transparent wall for the purpose of enabling direct vision through the catheter. Specifically Mikus et al. disclose, "Direct vision is accomplished by use of an endoscope in the central lumen of the insertion catheter which has a transparent catheter wall." At the time of the invention, it would have been obvious to one of ordinary skill in the art to equip the Zhu hemostat catheter with a transparent wall for the purpose of enabling direct vision through the catheter.

20. Claims 8 & 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu. Zhu disclose that the hemostat member is attached to a guidewire which is promulgated into the wound. It is extremely well known in the art that a guidewire torqueing device (push member) is used to grab and manipulate a guidewire for the purpose of more easily pushing a guidewire. At the time of the invention, it would have been obvious to one skilled in the art to use a guidewire torqueing device to manipulate and push the Zhu guidewire and balloon combination into the wound.

21. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu in view of Weinstein et al. US 5,370,660. Zhu discloses all of claim 10, but the Zhu device uses a balloon as the hemostat agent. In the percutaneous hemostat art, there are two alternate analogous structures balloons and sponges. Sponges and balloons perform the same function and have the same purpose in this art. Patents US 5.370.660, 6.325.789, 5.928.266, and 5.437.631 all disclose a sponge used as hemostat agent in a percutaneous hemostat device. For example, Weinstein et al. disclose (col. 4, line 53-60) that a collagen sponge can be used to help retard bleeding. At the time of the invention, it would have been obvious to one of ordinary skill in the art to substitute the well-known, Zhu hemostat (a balloon) for another well known Weinstein et al. hemostat (a sponge) because either material can be used to help retard bleeding.

22. Regarding claim 20, the combined Zhu-Weinstein device contains an expandable plug as described in (col. 4, 52-59.) The combined device clearly shows in figure 3 of the Weinstein et al. reference that the hemostat material is positioned by poking the material with the implement (guidewire, 26.)

23. Regarding claim 21, the plug of the combined device will contain two layers, a mesh layer (44-51), and a porous collagen sponge (or similar material.) The mesh, first layer, is composed of stainless steel, a material that is elastic. The second layer contains collagen, a material that acts as a hemostat.

24. Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined Zhu-Weinstein device in view of Hammerslag US 5.383.899. The combined Zhu-Weinstein device discloses a pushing member (item 24 in '660) that slides but the pushing member slides in the inside of the lumen as opposed to outside the lumen. The Hammerslag

reference discloses a pushing member (the rings (10) on figure 1) situated around the outside of the surgical device and comprising a lumen (26.) Hammerslag (col. 2, lines 65-66) states a pair of rings would improve the ease of gripping the pushing member. At the time of the invention, it would have been obvious to one of ordinary skill in the art to add the Hammerslag rings and push member to the combined Zhu-Weinstein device for the purpose of easing the gripping of the push member.

25. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu-Weinstein-Hammerslag device in view of the Zhu-Weldon device. The Zhu-Weinstein-Hammerslag device discloses all of claim 24, but does not disclose the use of an adhesive in conjunction with a hemostat. The combined Zhu-Weldon device discloses the use of hemostat glue that helps retard bleeding in conjunction with the balloon. Weldon discloses that although the hemostat/balloon could be used by itself, clotting would be hastened by first inflating the balloon and then pushing the adhesive agent out of the second lumen into the wound. Further, Weldon discloses the method of ejecting the second hemostat through the push member lumen into contact with the wound (since the first hemostat material is already in the wound, the second hemostat material inherently comes into contact with the first hemostat material.) At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the Zhu-Weinstein-Hammerslag device to use the Zhu-Weldon adhesive to hasten the healing time of the wound.

26. Regarding claim 26, the combined device of section 25 above, contains a pushing member. That pushing member would be designed to push adhesive fluid as taught by Weldon et al. into the hemostat.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6.325.789, 5.928.266, 5.437.631, 6.056.768, 6.287.322 all disclose percutaneous hemostat devices using sponges, balloons, and adhesives to retard bleeding at a puncture site.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Paul Roberts PR
January 31, 2003

MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700